

~~Drug sample~~

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Applicant: LEK Pharmaceuticals d.d.

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New claims 1 to 15

- 10 1. A rapidly disintegrating table containing:
amoxicillin and clavulanic acid silicified microcrystalline
cellulose as the disintegrant and optional excipients.
- 15 2. The rapidly disintegrating tablet according to claim
1, wherein the amoxicillin is in the form of amoxicillin
trihydrate.
- 20 3. The rapidly disintegrating tablet according to claim
1, wherein the clavulanic acid is in the form of potassium
clavulanate.
- 25 4. The rapidly disintegrating tablet according to any of
claims 1 to 3, wherein the ratio of amoxicillin to
clavulanic acid is in the range of 2:1 to 30:1.
5. The rapidly disintegrating tablet according to any of
claims 1 to 3, wherein the ratio of amoxicillin to
clavulanic acid is 4:1.
- 30 6. The rapidly disintegrating tablet according to any of
claims 1 to 3, wherein the ratio of amoxicillin to
clavulanic acid is 7:1.
- 35 7. The rapidly disintegrating tablet according to claim
1, wherein the proportion of the active substance in the
tablet is 5 to 70% by weight of the tablet.

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8. The rapidly disintegrating tablet according to claim 1, wherein the ratio of amoxicillin and clavulanic acid to the silicified microcrystalline cellulose is 0.5:1 to 2.5:1.
9. The rapidly disintegrating tablet according to claim 1, wherein the proportion of silicified microcrystalline cellulose is 30 to 95% by weight.
10. The rapidly disintegrating tablet according to claim 1, wherein hydrogenated castor oil is contained as a lubricant.
11. Use of the rapidly disintegrating tablet according to any of the preceding claims as an orodispersible tablet or as a dispersible tablet.
12. Use of the rapidly disintegrating tablet according to any of claims 1 to 10 in the manufacture of a medicament for the treatment of pediatric patients.
13. A tablet according to claims 1 to 10, which is orodispersible.
14. A tablet according to claims 1 to 10 which is dispersible.
15. A process for the manufacture of a rapidly disintegrating tablet according to claim 1 comprising the steps of:

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- blending amoxicillin, clavulanic acid, silicified microcrystalline cellulose as the disintegrant and optional excipients;
- homogenizing the obtained mixture;
- 5 • sieving the homogenized mixture; and
- forming tablets therefrom.

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